DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 00D–1562]

Guidance for Industry on Cancer Drug and Biological Products—Clinical Data in Marketing Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Cancer Drug and Biological Products—Clinical Data in Marketing Applications." This guidance provides recommendations for sponsors designing clinical trials to demonstrate the safety and efficacy of cancer treatments on the collection of data that can be submitted to support marketing claims in new drug applications (NDAs), biologics license applications (BLAs), or applications for supplemental indications.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. A faxed copy of this guidance can also be obtained by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

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Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

Grant A. Williams, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5740, or

Patricia Keegan, Center for Biologics Evaluation and Research (HFM–573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5093.

SUPPLEMENTARY INFORMATION:

I. Background

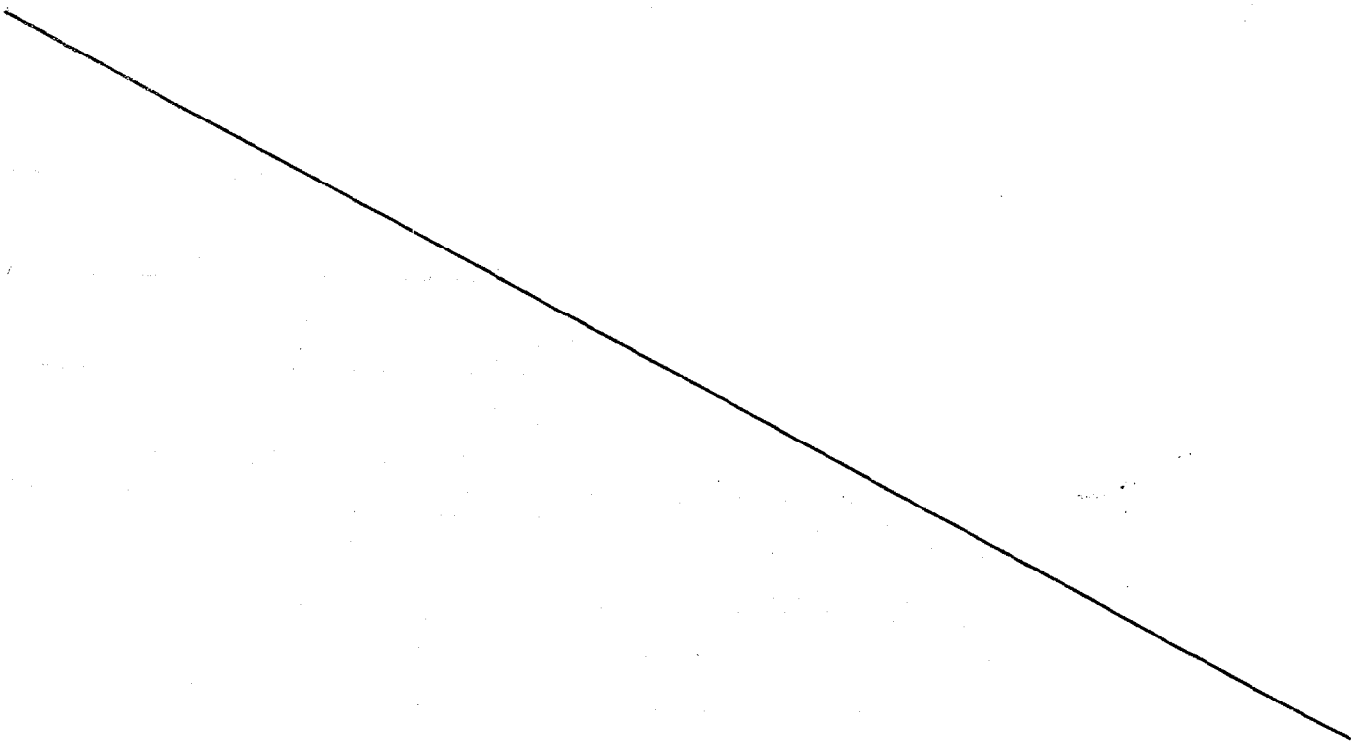
FDA is announcing the availability of a guidance for industry entitled "Cancer Drug and Biological Products—Clinical Data in Marketing Applications." This guidance provides general principles for data collection and submission for sponsors of investigational new drug applications, NDAs, BLAs, or supplemental applications for new indications. The guidance is intended to enable sponsors to more effectively create plans to record and report the data from controlled trials that form the clinical basis for approval of anticancer drug and biological products

In the **Federal Register** of November 9, 2000 (65 FR 67389), FDA announced the availability of a draft version of this guidance. After FDA considered public comments on the draft guidance, the agency determined that revision of the draft guidance was necessary. The final guidance notes that tumor images usually are not submitted as part of the marketing application, but this should be clarified at presubmission meetings with FDA. The final guidance also states that information on drug dosing should be collected from all patients rather than from a sample of patients, as suggested in the draft guidance. Collecting dosing information in all patients allows a full assessment of the adequacy of dosing in both the investigational arm and the control arm of the submitted studies.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on clinical data in marketing applications for cancer drug or biologic products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (address above). Two copies of written mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 9/28/01
September 28, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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